

**REMARKS**

Applicants respectfully request entry of the foregoing and reconsideration of the subject matter identified in caption, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, and in light of the remarks which follow.

Claims 26, 28-51, 53-54, 56-81, 83-84, 86-106, 108-111 and 113-120 are pending in the application, claims 25, 55 and 85 having been canceled above and new claims 115-120 having been added above.

By the above amendments, claims 26, 28-32, 34-37, 40, 45-47, 49, 51, 53, 56-62, 64-67, 70, 75-76, 79, 81, 83-84, 86-97, 100, 105, 106-107, 109, 111 and 113-114 have been amended to depend from new claims 115, 117 and 119. Claims 57 and 87 have been further amended by deleting "or prevention" so that these claims are consistent with the independent claims. Additionally, new claims 115-120 have been added to further define exemplary embodiments of the present invention. Support for new claims 115-120 can be found at least at page 14 of the specification.

Applicants thank the Examiner for the courtesies extended to their representatives, Norman H. Stepno, Mary Katherine Baumeister and Martin A. Bruehs, during the personal interview of March 11, 2003. In particular, Applicants thank the Examiner for indicating that new claims 115-120 would be favorably considered. The Examiner's Interview Summary provides a fair assessment of the issues discussed during the interview.

Additionally, Applicants thank the Examiner for acknowledging the filing under § 1.114 and for withdrawing the double patenting rejections in view of the Terminal Disclaimers.

Turning now to the Official Action, claims 25-26, 28, 32-34, 45-46, 51-52, 55-58, 62-64, 75-76, 85-88, 97, 101, 105-106, 111, 113 and 114 stand rejected under 35 U.S.C. § 102(b) as being anticipated by WO 93/14084. As independent claims 25, 55 and 85 have now been canceled, and because all of the remaining claims were dependent on these claims, this rejection is now moot. However, in an effort to expedite prosecution of the application, Applicants provide the following remarks with respect to new independent claims 115-120.

New claims 115, 117 and 119 define methods of treating sensitive skin that include topically applying a cosmetic/dermatological composition which comprises an effective amount of at least one active ingredient which causes the release of substance P in sensitive skin and an amount of at least one substance P antagonist effective to attenuate or eliminate such release of substance P. Additionally, new claims 116, 118 and 120 define methods of treating sensitive skin, wherein the sensitive skin has such amount of substance P already released therein as to cause neurogenic manifestations of dyesthesia.

It is well established, that in order to establish anticipation under 35 U.S.C. § 102(b), each element of the claim in issue must be found, either expressly described or under principles of inherency, in a single prior art reference. See Kalman v. Kimberly-Clark Corp., 218 USPQ 789 (Fed. Cir. 1983). That is not the case here.

For example, WO '084 fails to disclose or fairly suggest a cosmetic or dermatological method for treating sensitive skin that includes applying to said sensitive skin a cosmetic/dermatological composition which comprises an effective amount of at least one active ingredient which causes the release of substance P in sensitive skin and an

amount of at least one substance P antagonist effective to attenuate or eliminate such release of substance P, as defined in independent claims 115, 117 and 119. Additionally, WO '084 fails to disclose or fairly suggest a cosmetic or dermatological method for treating sensitive skin wherein the sensitive skin has such an amount of substance P already released therein as to cause neurogenic manifestations of dyesthesia, as defined in independent claims 116, 118 and 120.

Accordingly, Applicants submit that WO '084 fails to expressly or inherently describe each element of the claims in issue, and therefore fails to anticipate claims 115-120.

For at least these reasons, claims 115-120, and the claims depending therefrom, are not anticipated by WO '084. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 25-26, 28, 32-34, 45-46, 51-52, 55-58, 62-64, 75-76, 85-88, 97, 101, 105-106, 111, 113 and 114 stand rejected under 35 U.S.C. § 103 as being unpatentable over WO '084. Again, as independent claims 25, 55 and 85 have been canceled and because all of the remaining claims were dependent on these claims, this rejection is now moot. In an effort to expedite prosecution of the application, however, Applicants provide the following remarks.

For at least all of the reasons set forth above, Applicants submit that claims 115-120 also would not have been obvious over WO '084. That is, because WO '084 fails to disclose or fairly suggest a cosmetic or dermatological method for treating sensitive skin by applying to said sensitive skin a cosmetic/dermatological composition which comprises an

effective amount of at least one active ingredient which causes the release of substance P in sensitive skin and an amount of at least one substance P antagonist effective to attenuate or eliminate such release of substance P, Applicants submit that new claims 115, 117 and 119 would not have been obvious over WO '084. Similarly, because WO '084 fails to disclose or fairly suggest a cosmetic or dermatological method for treating sensitive skin having such amount of substance P already released therein as to cause neurogenic manifestation of dyesthesia, Applicants also submit that new claims 116, 118 and 120 would not have been obvious over WO '084.

For at least these reasons, claims 115-120, and the claims which depend therefrom, would not have been obvious over WO '084. Accordingly, reconsideration and withdrawal of the rejection are in order.

Claims 25-26, 28-51, 53-81, 83-111 and 113-114 stand rejected under 35 U.S.C. § 103 as being unpatentable over Wallengren (contact dermatitis), Wallengren (Br. J. Dermatitis) in combination with WO83/01252 and/or WO '084. As independent claims 25, 55 and 85 have now been canceled, and because all of the remaining claims were dependent on these claims, this rejection is now moot. However, in an effort to expedite prosecution of the application, Applicants provide the following remarks.

As explained above, new claims 115, 117 and 119 define cosmetic or dermatological methods for treating sensitive skin that include topically applying to the sensitive skin a cosmetic/dermatological composition comprising an effective amount of at least one active ingredient which causes the release of substance P in sensitive skin and an amount of at least one substance P antagonist effective to attenuate or eliminate such release

of substance P. Additionally, as explained above, new claims 116, 118 and 119 are directed to cosmetic or dermatological methods for treating sensitive skin, wherein the sensitive skin has such amount of substance P already released therein as to cause neurogenic manifestations of dyesthesia. Applicants submit that none of the cited references, either alone or in combination disclose or fairly suggest the methods of claims 115-120.

For at least these reasons, claims 115-120, and the claims which depend therefrom, would not have been obvious over Wallengren (contact dermatitis), Wallengren (BR. J. Dermatitis) in combination with WO '252 and/or WO '084. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

From the foregoing, Applicants earnestly solicit further and favorable action in the form of a Notice of Allowance.

If there are any questions concerning this paper or the application in general, Applicants invite the Examiner to telephone the undersigned at the Examiner's release convenience.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: 

Martin A. Bruehs  
Registration No. 45,635

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620  
Date: April 18, 2003

**Attachment to Amendment dated April 18, 2003**

**Marked-up Claims 26, 28-47, 49, 51, 53, 56-62, 64-67, 70, 75-77,  
79, 81, 83-84, 86-92, 94-97, 100, 105-107, 109, 111 and 113-114**

26. (Amended) The method of Claim [25] 115, wherein said substance P antagonist is a compound that (i) reduces the extravasation of plasma through the vascular wall caused by capsaicin or by antidromic nerve excitation, or (ii) inhibits the contraction of the smooth muscles induced by the administration of substance P, or (iii) a combination thereof, and wherein said effective amount of said at least one substance P antagonist is formulated into a topically applicable cosmetically-acceptable medium therefor.

28. (Amended) The method of Claim [25] 115, wherein the substance P antagonist is a nitrogen-containing heterocyclic compound.

29. (Amended) The method of Claim [25] 115, wherein said substance P antagonist is a peptide.

30. (Amended) The method of Claim [25] 115, wherein said substance P antagonist is a peptide selected from the group consisting of sendide and spantide II.

31. (Amended) The method of Claim [25] 115, wherein said substance P antagonist is selected from the group consisting of 2-tricyclyl-2-aminoethane, spirolactame, quinuclidine, azacyclic, aminopyrrolidine, piperidine, aminoazeheterocyclic and isoindole compounds.

**Attachment to Amendment dated April 18, 2003**

**Marked-up Claims 26, 28-47, 49, 51, 53, 56-62, 64-67, 70, 75-77,  
79, 81, 83-84, 86-92, 94-97, 100, 105-107, 109, 111 and 113-114**

32. (Amended) The method of Claim [25] 115, wherein the substance P antagonist is contained in an amount ranging from between 0.000001 to 5 percent by weight of the total weight of the composition.

34. (Amended) The method of Claim [25] 115, wherein said substance P antagonist is administered in a topically administrable form selected from the group consisting of aqueous and hydroalcoholic solutions, water-in-oil and oil-in-water emulsions, microemulsions, aqueous gels, anhydrous gels, serums and vesicular dispersions.

35. (Amended) The method of Claim [25] 115, wherein said substance P antagonist is co-administered with at least one agent selected from the group consisting of anti-bacterials, anti-parasitics, anti-fungals, anti-inflammatories, anti-pruriginous agents, anesthetics, anti-virals, keratolytic agents, anti-free radical agents, anti-seborrheal agents, dandruff-fighting agents, acne-fighting agents, skin differentiating modulating agents, skin proliferation modulating agents, and skin pigmentation modulating agents.

36. (Amended) The method of Claim [25] 115, wherein said substance P antagonist is co-administered with at least one agent selected from the group consisting of lidocaine, chlorhydrate, non-steroidal anti-parasitics, and anti-inflammatory agents.

**Attachment to Amendment dated April 18, 2003**

**Marked-up Claims 26, 28-47, 49, 51, 53, 56-62, 64-67, 70, 75-77,  
79, 81, 83-84, 86-92, 94-97, 100, 105-107, 109, 111 and 113-114**

37. (Amended) The method of Claim [25] 115, wherein said substance P antagonist is contained in a cosmetic or dermatological composition selected from the group consisting of cleansing creams, make-up removal creams, foundation creams, sunscreen creams, liquid foundations, make-up removal lotions, skin-care lotions, sunscreen lotions, skin-care gels, skin-care foams, tanning lotions, bath preparations, after-shave gels, after-shave lotions, depilatory creams, insect sting compositions, soaps, cleansing bars, aerosol compositions, hair care compositions, and mouth care compositions.

40. (Amended) The method of Claim [25] 115, wherein said substance P antagonist is contained in an emulsion.

45. (Amended) The method of Claim [25] 115, wherein said substance P antagonist is administered together with at least one additive selected from the group consisting of a water-absorbent or lipophilic gelling agent, water-absorbent or lipophilic active ingredient, preservative, antioxidant, solvent, perfume, filler, screen and coloring substance.

46. (Amended) The method of Claim [25] 115, wherein said substance P antagonist is administered together with at least one oil selected from the group consisting



**Attachment to Amendment dated April 18, 2003**

**Marked-up Claims 26, 28-47, 49, 51, 53, 56-62, 64-67, 70, 75-77,  
79, 81, 83-84, 86-92, 94-97, 100, 105-107, 109, 111 and 113-114**

of a mineral oil, vegetable oil, animal oil, synthetic oil, silicone-containing oil, and a fluorinated oil.

47. (Twice Amended) The method of Claim [25] 115, wherein said substance P antagonist is administered with at least one active ingredient selected from the group consisting of protein, protein hydrolyzates, amino acids, polyalcohols, urea, allantoin, sugars, sugar derivatives, vitamins, hydroxy acids, retinol, tocopherol, ceramides, essential oils, and salicylic acid.

49. (Amended) The method of Claim [25] 115, wherein said substance P antagonist is administered together with at least one active ingredient that elicits an irritant side effect.

51. (Amended) The method of Claim [25] 115, wherein said substance P antagonist is contained in a cosmetically-acceptable medium.

53. (Amended) The method of Claim [25] 115, wherein said sensitive skin is skin that is characterized by at least one symptom selected from the group consisting of tingling, burning, itching, and erythema after topical application of capsaicin.

**Attachment to Amendment dated April 18, 2003**

**Marked-up Claims 26, 28-47, 49, 51, 53, 56-62, 64-67, 70, 75-77,  
79, 81, 83-84, 86-92, 94-97, 100, 105-107, 109, 111 and 113-114**

56. (Amended) The method of Claim [55] 117, wherein said substance P antagonist is a compound that (i) reduces the extravasation of plasma through the vascular wall caused by capsaicin or by antidromic nerve excitation, or (ii) inhibits the contraction of the smooth muscles induced by the administration of substance P, or (iii) a combination thereof, and wherein said effective amount of said at least one substance P antagonist is formulated into a topically applicable cosmetically-acceptable medium therefor.
57. (Amended) The method of Claim [55] 117, wherein the method of treatment [or prevention] of sensitive, but not allergic, skin alleviates or prevents at least one neurogenic manifestation selected from the group consisting of skin irritation, desquamation, erythema, side effects of dysesthesia, side effects of overheating, and skin pruritus.
58. (Amended) The method of Claim [55] 117, wherein the substance P antagonist is a nitrogen-containing heterocyclic compound.
59. (Amended) The method of Claim [55] 117, wherein said substance P antagonist is a peptide.
60. (Amended) The method of Claim [55] 117, wherein said substance P antagonist is a peptide selected from the group consisting of sendide and spantide II.

**Attachment to Amendment dated April 18, 2003**

**Marked-up Claims 26, 28-47, 49, 51, 53, 56-62, 64-67, 70, 75-77,  
79, 81, 83-84, 86-92, 94-97, 100, 105-107, 109, 111 and 113-114**

61. (Amended) The method of Claim [55] 117, wherein said substance P antagonist is selected from the group consisting of 2-tricycyl-2-aminoethane, spirolactame, quinuclidine, azacyclic, aminopyrrolidine, piperidine, aminoazeheterocyclic and isoindole compounds.

62. (Amended) The method of Claim [55] 117, wherein the substance P antagonist is contained in an amount ranging from between 0.000001 to 5 percent by weight of the total weight of the composition.

64. (Amended) The method of Claim [55] 117, wherein said substance P antagonist is administered in a topically administrable form selected from the group consisting of aqueous and hydroalcoholic solutions, water-in-oil and oil-in-water emulsions, microemulsions, aqueous gels, anhydrous gels, serums and vesicular dispersions.

65. (Amended) The method of Claim [55] 117, wherein said substance P antagonist is co-administered with at least one agent selected from the group consisting of anti-bacterials, anti-parasitics, anti-fungals, anti-inflammatories, anti-pruriginous agents, anesthetics, anti-virals, keratolytic agents, anti-free radical agents, anti-seborrheal agents, dandruff-fighting agents, acne-fighting agents, skin differentiating modulating agents, skin proliferation modulating agents, and skin pigmentation modulating agents.

**Attachment to Amendment dated April 18, 2003**

**Marked-up Claims 26, 28-47, 49, 51, 53, 56-62, 64-67, 70, 75-77,  
79, 81, 83-84, 86-92, 94-97, 100, 105-107, 109, 111 and 113-114**

66. (Amended) The method of Claim [55] 117, wherein said substance P antagonist is co-administered with at least one agent selected from the group consisting of lidocaine, chlorohydrate, non-steroidal anti-parasitics, and anti-inflammatory agents.
67. (Amended) The method of Claim [55] 117, wherein said substance P antagonist is contained in a cosmetic or dermatological composition selected from the group consisting of cleansing creams, make-up removal creams, foundation creams, sunscreen creams, liquid foundations, make-up removal lotions, skin-care lotions, sunscreen lotions, skin-care gels, skin-care foams, tanning lotions, bath preparations, after-shave gels, after-shave lotions, depilatory creams, insect sting compositions, soaps, cleansing bars, aerosol compositions, hair care compositions, and mouth care compositions.
70. (Amended) The method of Claim [55] 117, wherein said substance P antagonist is contained in an emulsion.
75. (Amended) The method of Claim [55] 117, wherein said substance P antagonist is administered together with at least one additive selected from the group consisting of a water-absorbent or lipophilic gelling agent, water-absorbent or lipophilic active ingredient, preservative, antioxidant, solvent, perfume, filler, screen and coloring substance.

**Attachment to Amendment dated April 18, 2003**

**Marked-up Claims 26, 28-47, 49, 51, 53, 56-62, 64-67, 70, 75-77,  
79, 81, 83-84, 86-92, 94-97, 100, 105-107, 109, 111 and 113-114**

76. (Amended) The method of Claim [55] 117, wherein said substance P antagonist is administered together with at least one oil selected from the group consisting of a mineral oil, vegetable oil, animal oil, synthetic oil, silicone-containing oil, and a fluorinated oil.
77. (Twice Amended) The method of Claim [55] 117, wherein said substance P antagonist is administered with at least one active ingredient selected from the group consisting of protein, protein hydrolyzates, amino acids, polyalcohols, urea, allantoin, sugars, sugar derivatives, vitamins, hydroxy acids, retinol, tocopherol, ceramides, essential oils, and salicylic acid.
79. (Amended) The method of Claim [55] 117, wherein said substance P antagonist is administered together with at least one active ingredient that elicits an irritant side effect.
81. (Amended) The method of Claim [55] 117, wherein said substance P antagonist is contained in a cosmetically-acceptable medium.

**Attachment to Amendment dated April 18, 2003**

**Marked-up Claims 26, 28-47, 49, 51, 53, 56-62, 64-67, 70, 75-77,  
79, 81, 83-84, 86-92, 94-97, 100, 105-107, 109, 111 and 113-114**

83. (Amended) The method of Claim [55] 117, wherein said sensitive, but not allergic, skin is skin that is characterized by at least one symptom selected from the group consisting of tingling, burning, itching, and erythema after topical application of capsaicin.

84. (Amended) The method of Claim [83] 117, wherein said at least one symptom is observed between 3 and 20 minutes after capsaicin application.

86. (Amended) The method of Claim [85] 119, wherein said substance P antagonist is a compound that (i) reduces the extravasation of plasma through the vascular wall caused by capsaicin or by antidromic nerve excitation, or (ii) inhibits the contraction of the smooth muscles induced by the administration of substance P, or (iii) a combination thereof, and wherein said effective amount of said at least one substance P antagonist is formulated into a topically applicable cosmetically-acceptable medium therefor.

87. (Amended) The method of Claim [85] 119, wherein the method of treatment [or prevention] of capsaicin-sensitive skin alleviates or prevents at least one neurogenic manifestation selected from the group consisting of skin irritation, desquamation, erythema, side effects of dysesthesia, side effects of overheating, and skin pruritus.

**Attachment to Amendment dated April 18, 2003**

**Marked-up Claims 26, 28-47, 49, 51, 53, 56-62, 64-67, 70, 75-77,  
79, 81, 83-84, 86-92, 94-97, 100, 105-107, 109, 111 and 113-114**

88. (Amended) The method of Claim [85] 119, wherein the substance P antagonist is a nitrogen-containing heterocyclic compound.
89. (Amended) The method of Claim [85] 119, wherein said substance P antagonist is a peptide.
90. (Amended) The method of Claim [85] 119, wherein said substance P antagonist is a peptide selected from the group consisting of sendide and spantide II.
91. (Amended) The method of Claim [85] 119, wherein said substance P antagonist is selected from the group consisting of 2-tricyclyl-2-aminoethane, spirolactame, quinuclidine, azacyclic, aminopyrrolidine, piperidine, aminoazeheterocyclic and isoindole compounds.
92. (Amended) The method of Claim [85] 119, wherein the substance P antagonist is contained in an amount ranging from between 0.000001 to 5 percent by weight of the total weight of the composition.
94. (Amended) The method of Claim [85] 119, wherein said substance P antagonist is administered in a topically administrable form selected from the group

**Attachment to Amendment dated April 18, 2003**

**Marked-up Claims 26, 28-47, 49, 51, 53, 56-62, 64-67, 70, 75-77,  
79, 81, 83-84, 86-92, 94-97, 100, 105-107, 109, 111 and 113-114**

consisting of aqueous and hydroalcoholic solutions, water-in-oil and oil-in-water emulsions, microemulsions, aqueous gels, anhydrous gels, serums and vesicular dispersions.

95. (Amended) The method of Claim [85] 119, wherein said substance P antagonist is co-administered with at least one agent selected from the group consisting of anti-bacterials, anti-parasitics, anti-fungals, anti-inflammatories, anti-pruriginous agents, anesthetics, anti-virals, keratolytic agents, anti-free radical agents, anti-seborrheal agents, dandruff-fighting agents, acne-fighting agents, skin differentiating modulating agents, skin proliferation modulating agents, and skin pigmentation modulating agents.

96. (Amended) The method of Claim [85] 119, wherein said substance P antagonist is co-administered with at least one agent selected from the group consisting of lidocaine, chlorhydrate, non-steroidal anti-parasitics, and anti-inflammatory agents.

97. (Amended) The method of Claim [85] 119, wherein said substance P antagonist is contained in a cosmetic or dermatological composition selected from the group consisting of cleansing creams, make-up removal creams, foundation creams, sunscreen creams, liquid foundations, make-up removal lotions, skin-care lotions, sunscreen lotions, skin-care gels, skin-care foams, tanning lotions, bath preparations, after-shave gels,



**Attachment to Amendment dated April 18, 2003**

**Marked-up Claims 26, 28-47, 49, 51, 53, 56-62, 64-67, 70, 75-77,  
79, 81, 83-84, 86-92, 94-97, 100, 105-107, 109, 111 and 113-114**

after-shave lotions, depilatory creams, insect sting compositions, soaps, cleansing bars, aerosol compositions, hair care compositions, and mouth care compositions.

100. (Amended) The method of Claim [85] 119, wherein said substance P antagonist is contained in an emulsion.

105. (Amended) The method of Claim [85] 119, wherein said substance P antagonist is administered together with at least one additive selected from the group consisting of a water-absorbent or lipophilic gelling agent, water-absorbent or lipophilic active ingredient, preservative, antioxidant, solvent, perfume, filler, screen and coloring substance.

106. (Amended) The method of Claim [85] 119, wherein said substance P antagonist is administered together with at least one oil selected from the group consisting of a mineral oil, vegetable oil, animal oil, synthetic oil, silicone-containing oil, and a fluorinated oil.

107. (Twice Amended) The method of Claim [85] 119, wherein said substance P antagonist is administered with at least one active ingredient selected from the group consisting of protein, protein hydrolyzates, amino acids, polyalcohols, urea, allantoin,

**Attachment to Amendment dated April 18, 2003**

**Marked-up Claims 26, 28-47, 49, 51, 53, 56-62, 64-67, 70, 75-77,  
79, 81, 83-84, 86-92, 94-97, 100, 105-107, 109, 111 and 113-114**

sugars, sugar derivatives, vitamins, hydroxy acids, retinol, tocopherol, ceramides, essential oils, and salicylic acid.

109. (Amended) The method of Claim [85] 119, wherein said substance P antagonist is administered together with at least one active ingredient that elicits an irritant side effect.

111. (Amended) The method of Claim [85] 119, wherein said substance P antagonist is contained in a cosmetically-acceptable medium.

113. (Amended) The method of Claim [85] 119, wherein capsaicin-sensitive skin is skin that is characterized by at least one symptom selected from the group consisting of tingling, burning, itching, and erythema after topical application of capsaicin.

114. (Amended) The method of Claim [85] 119, wherein said at least one symptom is observed between 3 and 20 minutes after capsaicin application.